



KANSAS DRUG UTILIZATION REVIEW NEWSLETTER

Health Information Designs, LLC

Winter 2016

Welcome to the Winter 2016 edition of the "Kansas Drug Utilization Review Newsletter," published by Health Information Designs, LLC (HID). This newsletter is part of a continuing effort to keep the Medicaid provider community informed of important changes in the Kansas Medical Assistance Program (KMAP).

Helpful Web Sites

KMAP Web Site

<https://www.kmap-state-ks.us/>

KDHE-DHCF Web Site

<http://www.kdheks.gov/hcf/>

KanCare Web Site

<http://www.kancare.ks.gov/>

Fee-For-Service (FFS)

Helpful Numbers

Provider Customer Service (Provider Use Only)

1-800-933-6593

Beneficiary Customer Service

1-800-766-9012

KMAP PA Help Desk

1-800-285-4978

In This Issue

Summary of PCSK9 Inhibitors

Preferred Drug List Updates

New and Upcoming Generic
Medications

Proprotein Convertase Subtilisin Kexin type 9 (PCSK9) Inhibitors

The FDA recently approved Repatha™ (evolocumab) and Praluent® (alirocumab), which are monoclonal antibodies that inactivate proprotein convertase subtilisin-kexin type 9 (PCSK9). They are typically indicated as adjunct therapy to diet, exercise, and maximally tolerated statin therapy for the treatment of certain forms of hyperlipidemia. These medications are completely different from conventional hyperlipidemia therapies, which usually consist of a daily oral medication. Repatha and Praluent are given as subcutaneous injections every two weeks; Repatha can even be given monthly at a higher dose. They work by inhibiting PCSK9, thereby decreasing LDL-receptor degradation and re-circulating the receptors to the surface of the liver cells. This ultimately lowers LDL levels in the blood by increasing the number of receptors available to clear LDL from the body.

Repatha is indicated to treat heterozygous familial hypercholesterolemia (HeFH), clinical atherosclerotic disease (CVD), and homozygous familial hypercholesterolemia (HoFH). Adjunct therapies for treatment of HeFH and CVD are diet, exercise, and maximally-tolerated statin therapy; any LDL-lowering therapy can be used in place of statins in patients with HoFH. Praluent® is only indicated to treat HeFH and CVD as an adjunct to diet, exercise, and maximally-tolerated statin therapy.

Studies conducted on both of these drugs have proven that they are very effective at lowering LDL levels. Praluent was evaluated through five different placebo-controlled trials. The patients treated with Praluent in these trials saw an average LDL reduction of 36-59% compared to placebo groups. These participants had HeFH or CVD with high risk of heart attack and stroke, and were taking a maximally tolerated dose of statins. Repatha® was evaluated through nine different placebo-controlled trials, with some specifically enrolling patients with either HeFH or HoFH. Patients treated with Repatha in trials saw approximately 60% reduction in LDL levels.

Proprotein Convertase Subtilisin Kexin type 9 (PCSK9) Inhibitors cont.

The benefits of these drugs have been shown in terms of reduction in LDL levels in the blood, but the effect of the drugs alone on cardiovascular events has not been established. If the drugs are given with a maximally-tolerated statin, and cardiovascular events were prevented, it would be unknown how much of an effect the PCSK9 inhibitors played as statins have a known cardiovascular benefit. Therefore, benefits of these drugs on morbidity and mortality cannot be determined.

	Repatha		Praluent
Disease State	HeFH/CVD	HoHF	HeHF/CVD
Dosing and Administration	140 mg SubQ every 2 weeks 420 mg SubQ once monthly (3 injections given consecutively within 30 minutes)	420 mg SubQ once monthly (3 injections given consecutively within 30 minutes)	75 mg SubQ every 2 weeks 150 mg SubQ every 2 weeks (if response is inadequate)
Dosage Form	140 mg/mL solution in single-use prefilled syringe 140 mg/mL solution in a single-use prefilled SureClick® autoinjector		75 mg/mL single-use prefilled syringe 150 mg/mL single-use prefilled syringe 75 mg/mL single-use pre-filled pen 150 mg/mL single-use pre-filled pen
Pregnancy/Breastfeeding	Antibodies are known to cross the placenta and exposure to the fetus is expected. It is not known if drug can be detected in breast milk.		
Geriatric Use	No dosing adjustments. Follow adult dosing		
Pediatric Use	Can be used in HoFH patients ≥ 13 years old with adult dosing		Not approved for pediatric use
Renal Impairment	No dose adjustments in mild to moderate impairment. Severe impairment (GFR <30) has not been studied		
Hepatic Impairment	No dose adjustments in mild to moderate impairment. Severe impairment (Child Pugh class C) has not been studied		
Common ADRs	Nasopharyngitis, injection site reactions, upper respiratory tract infections, influenza		
Drug Interactions	Contraindicated with belimumab		
Limitations	The effect on cardiovascular morbidity and mortality has not been established in any studies		

References:

1. Everett BM, Smith RJ, Hiatt WR. Reducing LDL with PCSK9 inhibitors – the clinical benefit of lipid drugs. *N Engl J Med* 2015; 373:1588-1591.
2. Pahon, E. “FDA News Release: FDA approves Praluent to treat certain patients with high cholesterol”. Press Announcements. United States Food and Drug Administration, 24 July 2015. Web. Accessed on 04 Feb 2016.
3. Pahon, E. “FDA News Release: FDA approves Repatha to treat certain patients with high cholesterol”. Press Announcements. United States Food and Drug Administration, 27 Aug 2015. Web. Accessed on 04 Feb 2016.
4. Praluent® (alirocumab) [package insert]. Bridgewater, NJ: Sanofi US and Regeneron Pharmaceuticals, Inc.; 2015.
5. Repatha™ (evolocumab) [package insert]. Thousand Oaks, CA: Amgen Inc.; 2015.

PCSK9 Coverage for the Medicaid Population in the State of Kansas

Currently, both of the PCSK9 Inhibitors listed above require a prior authorization (PA) and can be found on the state website at http://www.kdheks.gov/hcf/pharmacy/pa_criteria.htm. With new emerging LDL-lowering agents, the state of Kansas is in constant review of literature and presents changes to PA criteria in front of the quarterly Drug Utilization Review (DUR) board to approve updates for proper usage, when applicable. Repatha is the preferred agent on the Preferred Drug List (PDL).

Updates to the Preferred Drug List

Drug list updated March 1, 2016. Preferred agents listed include the generic formulations, when applicable.

ACE Inhibitors: Altace® is now preferred

Proton Pump Inhibitors: Prevacid® suspension is now non-preferred

Inhaled Long-Acting Beta-Agonists/Anticholinergic Combinations: Anoro Ellipta® and Stiolto Respimat® are preferred

Long-Acting Opioids: Avinza® is now non-preferred

Anticoagulants: Savaysa® is non-preferred

Combination Products for Hyperlipidemia: Liptruzet® as been removed

Hepatitis C Antiviral Agents: Daklinza® and Technivie® are now preferred

Alphaglucoosidase Inhibitors: Precose is now preferred

Long-Acting Insulin: Toujeo Solostar® is non-preferred

SGLT2 Inhibitors: Farxiga® is now non-preferred and Jardiance® is now preferred

Anaphylaxis Agents: Epipen® and Epipen JR® are preferred and AdrenaClick® and epinephrine auto injectors are non-preferred

Injectable Methotrexate: Rasuvo® is preferred

Opioid-Induced Constipation Agents: Movantik® is preferred and Relistor® is non-preferred

PCSK9 Inhibitors: Repatha® is preferred and Praluent® is non-preferred

Thrombopoietin (PTO) Receptor Agonists: Nplate® is preferred and Promacta® is non-preferred

New and Upcoming Generic Medications

Recently Approved Generic Drugs:

November 2015	December 2015	January 2016
Nevirapine ER tablets (Viramune XR) Mesalamine rectal suppository (Canasa) Clozapine orally disintegrating tablets (Fazaclo)	Imatinib tablets (Gleevec) Olopatadine 0.1% ophthalmic solution (Patanol) Fesoterodine ER tablets (Toviaz)	Adapalene topical solution (Differin Topical Solution [Pledgets]) Naftifine HCL cream 2% (Naftin Cream) Deferasirox Tablets for Oral Suspension (Exjade) Milnacipran tablets (Savella)

Upcoming Generic Drugs:

Generic Name	Brand Name	Anticipated Launch
Aripiprazole	Abilify Discmelt	Second Half 2015
Methylphenidate	Daytrana	Second Half 2015
Aprepitant	Emend	Second Half 2015
Fenofibrate	Fenoglide	October 2015
Frovatriptan	Frova	October 2015
Ethinyl Estradiol/Norgestimate	Ortho Tri-Cyclen Lo	December 31, 2015
Dutasteride/Tamsulosin	Jalyn	Fourth Quarter 2015
Dutasteride	Avodart	Fourth Quarter 2015
Metformin	Glumetza	February 1, 2016
Darifenacin	Enablex	March 15, 2016
Rosuvastatin	Crestor	May 2, 2016

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